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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/528,456

03/18/2005

Solange Akselrod

29429

4917

67801

7590

02/24/2009

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EXAMINER

MANUEL, GEORGE C

ART UNIT

PAPER NUMBER

3762

MAIL DATE

DELIVERY MODE

02/24/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/528,456	<b>Applicant(s)</b> AKSELROD ET AL.	
	<b>Examiner</b> George Manuel	<b>Art Unit</b> 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-342 is/are pending in the application.
- 4a) Of the above claim(s) 127-342 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-126 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/28/08, 1/11/09, 1/18/09</u>                                | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

***Election/Restrictions***

Applicant's election with traverse of Group I (claims 1-126) in the reply filed on 11/28/08 is acknowledged. The traversal is on the ground(s) that there is not a serious search burden to search all claims. This is not found persuasive because the apparatus or system claims do not have the equivalent extent of a search as the method claims.

The requirement is still deemed proper and is therefore made FINAL.

Claims 127-342 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 11/28/08.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-20, 28-80 and 96-126 are rejected under 35 U.S.C. 103(a) as being unpatentable over Verrier et al (US 5,902,250) in view of Verrier et al (US 5,265,617).

Verrier et al '250 disclose a method of determining sleep states of a patient comprising the steps of: monitoring heart rate variability of the patient; and dynamically determining the sleep state of the patient based on the heart rate variability. Heart rate variability includes determining chest wall impedance of the patient and further includes monitoring the breathing pattern of the patient from the frequency of eyelid movements and from heart rate variability.

Verrier et al '250 further teach monitoring a frequency of eyelid movements and determining the breathing pattern based also on the frequency of eyelid movements.

FIG. 3 is a graph illustrating typical low frequency/high frequency (LF/HF) heart rate variability ratios for awake and sleep states.

FIG. 4 is a graph illustrating a relationship between heart rate and eyelid movement frequency during sleep.

Verrier et al '617 teach the amplitude of beat-to-beat alternation represents cardiac electrical instability. R-R intervals are analyzed to estimate a magnitude of a high frequency component of heart rate variability and to estimate a magnitude of a low frequency component of heart rate variability. The high frequency component indicates parasympathetic activity. The low frequency component indicates combined sympathetic activity and parasympathetic activity. The amplitude of beat-to-beat alternation, the high frequency component of heart

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rate variability, and the low frequency component of heart rate variability are simultaneously analyzed to diagnose cardiac electrical instability. Verrier et al '617 further teach traditional methods of quantifying heart rate variability have relied on power spectrum (Fourier) analysis.

One of ordinary skill in the art would have found it obvious to combine the teachings of Verrier et al '250 and Verrier et al '617 to analyze R-R intervals to estimate a magnitude of a high frequency component of heart rate variability and to estimate a magnitude of a low frequency component of heart rate variability for determining a slow-wave sleep period and a non-slow-wave-sleep period, and sleep apnea.

Claims 21-27 and 81-95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Geva et al (US 2004/0073098).

Geva et al disclose a method and system for processing and analyzing biomedical signals, such as ElectroCardiogram (ECG), ElectroEncephalogram (EEG), Electro-Oculogram (EOG), Electromyogram (EMG), Oximetry and Respiratory signals.

Geva et al teach body and electrode movements, rapid eye movements and eye blinks are temporal events that are detectable through differences from a contemporary ongoing EEG signal by using their energy, skewness, duration and fundamental frequency. One of ordinary skill in the art would have found it obvious to obtain an R-wave duration function based on the teaching that in order to avoid wasting processing time on signals that do not resemble

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heartbeats, a first classification process is employed (202) on the current Beat Under Test (BUT) 201.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George Manuel whose telephone number is (571) 272-4952.

/George Manuel/  
George Manuel  
Primary Examiner  
Art Unit: 3762

2/24/2009